

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203231Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

24 July 2012

NDA: 203-231/N-000

Drug Product Name

Proprietary: Not applicable

Non-proprietary: Zoledronic Acid Injection

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
6 January 2012	9 January 2012	9 January 2012	3 February 2012
19 July 2012	19 July 2012	N/A	N/A

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: ACS Dobfar Info SA
C/O Sagent Pharmaceuticals, Inc.

Address: 1901 North Roselle, Rd. Suite 700
Schaumburg, IL 60195-3176

Representative: Jeffrey P. Scheithe
Senior Manager of Regulatory Affairs

Telephone: 847-908-1625

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** 505(b)(2) application – standard review
 - 2. SUBMISSION PROVIDES FOR:** [REDACTED] (b) (4)
 - 3. MANUFACTURING SITE:** ACS Dobfar Info SA
CH – 7748 Campascio
Switzerland
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Aqueous solution in flexible 100 mL bags
 - 4 mg/100 mL
 - Intravenous
 - 5. METHOD(S) OF STERILIZATION:** [REDACTED] (b) (4)
 - 6. PHARMACOLOGICAL CATEGORY:** Treatment for hypercalcemia of malignancy
- B. SUPPORTING/RELATED DOCUMENTS:** N/A
- C. REMARKS:** The document was submitted in eCTD format. A product quality microbiology information request was submitted to the applicant on 11 July 2012. A response to the information request was provided on 19 July 2012.

filename: N203231r1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability -**
NDA 203-231 is recommended for approval on from the standpoint of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**
Not applicable

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -**
The drug product will be filled in 100 mL flexible bags and (b) (4).
- B. Brief Description of Microbiology Deficiencies -**
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable

III. Administrative

- A. Reviewer's Signature** _____
Stephen E. Langille, Ph.D.
Senior Microbiology Reviewer
- B. Endorsement Block** _____
John Metcalfe, Ph.D.
Senior Microbiology Reviewer
- C. CC Block**
N/A

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/s/

STEPHEN E LANGILLE
07/24/2012

JOHN W METCALFE
07/24/2012
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 203231

**Applicant: Sagent
Pharmaceuticals, Inc.**

Letter Date: 6 January 2012

**Drug Name: Zoledronic Acid
Injection**

NDA Type: 505b2

Stamp Date: 9 January 2012

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		X	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		The drug product is not preserved. Integrity test studies were provided in section 3.2.P.2
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		
7	Has the applicant submitted the results of analytical method verification studies?	X		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?			No such requests were made from the NDMS.
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The NDA was submitted in eCTD format.

Stephen E. Langille - Reviewing Microbiologist

Date

Bryan Riley - Microbiology
Secondary Reviewer/Team Leader

Date

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

STEPHEN E LANGILLE
02/17/2012

BRYAN S RILEY
02/17/2012
I concur.